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In the Supreme Court of the United States

OCTOBER TERM, 1978

PETER H. FORSHAM, ET AL., PETITIONERS

v.

PATRICIA R. HARRIS, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS

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OPINIONS BELOW

The opinion of the court of appeals (App. 217-257) is reported at 587 F.2d 1128. The order of the district court (App. 180-181) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on July 11, 1978. A petition for rehearing was denied on October 17, 1978 (App. 258-260). The petition for a writ of certiorari was filed on January 15, 1979, and was granted on May 14, 1979. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Freedom of Information Act requires an agency to acquire and make available to the public records generated, owned and possessed by a private, non-government group, where (a) the records were prepared in the course of a study that received a federal financial assistance grant, (b) in proposing regulatory action the agency relied on a public report of the study based on the records, and (c) the agency has a right under the grant to inspect the records.

STATUTE INVOLVED

5 U.S.C. 552 provides in part:

> (a)(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.
>
> * * * * *
>
> (a)(4)(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. * * *

STATEMENT

1. In mid-1959 a group of private, non-government physicians and scientists specializing in the treatment of diabetes at 12 participating clinics formed the University Group Diabetes Program (UGDP) to perform a long-term study comparing the incidence and development of degenerative complications of diabetes mellitus (App. 145-146). Initially, the UGDP study involved four treatment regimens: (1) diet alone; (2) diet plus insulin in standard dose; (3) diet plus insulin in variable dose; and (4) diet plus tolbutamide. In 1963 a fifth regimen was added: diet plus phenformin hydrochloride (App. 146). Tolbutamide and phenformin are administered orally and belong to a class of drugs known as "oral hypoglycemic" drugs.[1]

Since 1961 the UGDP study has received federal funding from the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) under the Public Health Service Act, 42 U.S.C. 241(c) (App. 145-147). Representatives of NIAMDD evaluated the design, methods and objectives of the study in its formative stages and periodically reviewed UGDP progress reports in connection with grant renewals (App. 146-147). However, management of

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[1] Oral hypoglycemic drugs fall into two categories: the sulfonylurea category (represented by tolbutamide) and the biguanide category (represented by phenformin hydrochloride). Both categories of drugs reduce blood-sugar levels in diabetic patients but operate through different biological mechanisms. See 40 Fed. Reg. 28587 (1975).

the day-to-day operations of the study remained the responsibility of UGDP. NIAMDD's supervision of the grantee's funded activities was generally limited to review of the periodic reports submitted by UGDP (see 45 C.F.R. 74.80, 74.82) (App. 147). The Food and Drug Administration was not involved in the planning, implementation, or design of the study (App. 146).[2]

By 1973, based on observations of over 1000 diabetes patients, the UGDP study had generated approximately 55 million documents. At all times these patient records have been in the possession of UGDP (App. 148). This information belongs to UGDP, and the NIAMDD grants and related regulations do not purport to shift ownership to the agency (App. 147, 180, 198). Moreover, although NIAMDD has a right to inspect the data to ensure compliance with the grant (see 45 C.F.R. 74.24), it has never seen or had possession of the originals or copies of the patient records (App. 148).

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[2] The National Institute of Arthritis, Metabolism and Digestive Disorders is one of several Institutes of the National Institutes of Health (NIH). It is authorized by statute to conduct and fund research on diabetes and other diseases. 42 U.S.C. 289a, 289c-1. The Food and Drug Administration (FDA) is a separate agency charged with enforcement of the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, including requirements for the labeling of drug products. NIAMDD and FDA are components of the Public Health Service, which is itself a part of the Department of Health, Education, and Welfare. See Reorganization Plan No. 3 of June 25, 1966, 31 Fed. Reg. 8855, and Reorganization Order of April 1, 1968, 33 Fed. Reg. 5426.

2. The Food and Drug Administration has initiated two proceedings to regulate oral hypoglycemic drugs. First, FDA has proposed to require a warning on the use of such drugs.[3] In 1970, UGDP reported a finding that the administration of tolbutamide to adults who had developed mild cases of diabetes led to a death rate from cardiovascular disease higher than that of a group treated with diet alone or with a fixed or variable dosage of insulin (App. 6, 222).[4] In 1971, UGDP reported a similar finding on phenformin.[5] Four years later, UGDP reported in more detail that phenformin-treated groups developed increased blood pressure levels and heart rate, thus suggesting that the drug might influence cardiovascular mortality.[6] Based in part on these reports, FDA proposed to require a label warning that oral

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[3] Pursuant to 21 U.S.C. 352(a), (f), 355(b), (d)(6) and (e)(3), FDA regulates the content of drug labeling. In practice, labeling includes detailed literature prepared and distributed by manufacturers to instruct physicians on the use of the drug. See 21 C.F.R. 201.100.

[4] Klimt, Knatterud, Meinert & Prout, *The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-onset Diabetes*, 19 Diabetes 747 (Supp. 2, 1970).

[5] UGDP, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes. IV. A Preliminary Report on Phenformin Results*, 217 J.A.M.A. 777-784 (1971).

[6] UGDP, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes. V. Evaluation of Phenformin Therapy*, 24 Diabetes 64-184 (Supp. 1, 1975).

hypoglycemics should be used only in cases of adult-onset, stable diabetes that could not be treated adequately by diet and/or insulin. 40 Fed. Reg. 28587, 28591 (1975). This proposal has not yet become final.[7]

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[7] The FDA first proposed label changes for tolbutamide and other sulfonylurea drugs in 1971. FDA Drug Bulletin (June 23, 1971). In response to criticisms of the UGDP study within the scientific community, NIAMDD contracted in 1972 with the Biometric Society, a private international society of biostatisticians, for an in-depth independent assessment of the quality of the UGDP study (App. 148). The Biometric Society reviewed a portion of the original patient data, among other things, and concluded that the "UGDP trial has raised suspicions [concerning the adverse effects of oral hypoglycemic drugs] which cannot be dismissed on the basis of other evidence presently available" and that "we consider the evidence of harmfulness moderately strong." *Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents*, 231 J.A.M.A. 583-608, 599 (1975). The contract with the Biometric Society did not require either that the Society seek access to the UGDP raw data or that any raw data that it did review be transmitted to NIAMDD. At the conclusion of its assessment, the Society did not submit to NIAMDD any raw data pertaining to UGDP (App. 148).

On July 7, 1975, the FDA published a summary of the findings of the Biometric Society, restated its intention to require the labeling change (including a label change for phenformin), and invited public comment. 40 Fed. Reg. 28587 (1975). Thereafter, in response to further criticisms of the UGDP study and of the Society's audit (see App. 250-251 n.17), the FDA (pursuant to a delegation of NIAMDD's authority to audit grantee records) conducted its own audit of the UGDP study. The FDA's audit team's conclusions were similar to those of the Biometric Society: although there were some errors and some discrepancies between the data file of the UGDP study and the published reports, the errors were not of sufficient frequency or magnitude to invalidate the finding that cardiovascular mortality was higher in the groups of

Second, on July 25, 1977, in light of numerous reports on the dangers of phenformin, the Secretary (acting pursuant to the imminent-hazard provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) suspended approval of new drug applications for phenformin until completion of administrative proceedings on the withdrawal of the applications.[8] On November 15, 1978, the FDA found that phenformin was not shown to be safe and ordered it withdrawn from the market. This decision, which superseded the Secretary's imminent-hazard order, was not based substantially on the UGDP study.[9]

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patients treated with tolbutamide plus diet and phenformin plus diet than in the groups treated with placebo or insulin. In conducting this audit, the FDA examined and copied a small but statistically adequate sample of the UGDP raw data. On November 14, 1978, FDA announced that its audit report was available for public inspection and that it had reopened the comment period on the labeling changes. 43 Fed. Reg. 52733 (1978). At the request of various parties the comment period has been further extended to September 14, 1979, and the labeling change has not yet become final and effective. 44 Fed. Reg. 42714 (1979).

[8] Contrary to petitioners' argument (Br. 17), the Secretary's order was not based "primarily" on the UGDP "data." The UGDP data were not examined by the Secretary at all. Instead, the UGDP *study* was listed as one of many reporting the dangerous effects of phenformin. See Order of the Secretary of Health, Education and Welfare, July 25, 1977, at 8-9.

[9] The order of the Commissioner of Food and Drugs, dated November 15, 1978, stated in part (44 Fed. Reg. 20969 (1979)):

> I affirm the Administrative Law Judge's ruling on the motion to strike the UGDP data. The Administrative Law Judge held that the "lack of availability of underlying data casts considerable doubt on the reliability of the

UGDP conclusions from an evidentiary standpoint. To the extent such data was not made available, the UGDP conclusions cannot be considered as substantiated on the record." * * * Accordingly, in reviewing the Bureau's evidence on the question of safety, the Administrative Law Judge referenced the UGDP study in only one paragraph of his 8-page summary. Initial Decision, at 20.

The Administrative Law Judge concluded that the UGDP study could be used for two purposes: to raise questions about the safety of phenformin and as the basis for expert opinion. The FDA has long taken the position that evidence suggestive of a lack of safety may be considered in evaluating whether a drug has been shown to be safe even though the evidence does not meet the standards required to establish the safety of the drug. The Administrative Law Judge's ruling that the UGDP study might serve as the basis for expert testimony is supported by Rule 703 of the Federal Rules of Evidence, which provides that even if data are not admissible into evidence they may nevertheless form the basis of opinions by experts if they are the type of data reasonably relied upon by experts in that particular field.

* * * * *

The record in this proceeding includes nearly 400 articles published in the medical literature. Many of them report studies on phenformin. None of those articles is accompanied by the "raw data" upon which it is based. The Bureau has relied solely on the published report of the UGDP study in the same way that it has relied upon the other published articles that were admitted into evidence. 21 C.F.R. 12.85 requires only that the Bureau provide data upon which it relies; it does not require the Bureau to submit related data on which it does not rely.

Because of CCD's emphasis on the unavailability of the raw data underlying the UGDP study, I have reviewed the testimony of the Bureau of Drugs' expert witnesses and find that their reliance upon the UGDP study was not substantial and cannot reasonably be characterized as pivotal to the opinions expressed by those witnesses.

44 Fed. Reg. 20967-20991 (1979).[10]

3. Petitioners are three members of the Committee on the Care of the Diabetic (CCD), an unincorporated association of physicians who treat diabetes, who contend that the UGDP study is unreliable (App. 4).[11] Prior to September 30, 1975, CCD made several Freedom of Information Act requests to the FDA and NIAMDD for access to, among other things, the UGDP original raw patient data (App. 40, 42-43, 49-52, 55-56, 59-60, 61-62). Both agencies responded that neither they nor any other branch of HEW had seen or possessed the materials requested, that the data belonged to UGDP, a private group, and therefore were not "agency records," and that the agencies were not required to acquire and produce them under the FOIA (App. 54, 57). All other requested documents related to the study in the possession of the agencies, including a limited sample of the patient data acquired by the FDA and the UGDP draft

[10] On April 10, 1979, the court of appeals held that petitioners lack standing to challenge the FDA's withdrawal of phenformin's new drug application. The court also held that this disposition rendered moot the appeal from the district court's denial of a preliminary injunction against the Secretary's imminent-hazard order. *Forsham* v. *Califano*, Nos. 77-2072 and 78-2288 (D.C. Cir. filed Apr. 10, 1979).

[11] Petitioners present their side of this controversy in considerable detail. Because the controversy is irrelevant to petitioners' claims under the Freedom of Information Act (see page 49, *infra*), we see no need to engage in an academic debate on the subject. The arguments in support of the UGDP findings may be found in references listed at App. 250 n.15.

and final reports, were made available to CCD (App. 143, 225).

On September 30, 1975, petitioners filed this FOIA suit in the United States District Court for the District of Columbia to require HEW to acquire and make available to them all of the raw patient data compiled by UGDP (App. 1).[12] The district court granted summary judgment in favor of the defendants, holding that the patient data are not "agency records" within the meaning of the FOIA (App. 180-181; footnote omitted):

> [T]he Court finds that (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) * * *; (2) the raw data in question is the property of the individual investigators and UGDP study coordinating center and remains in the possession, custody and control of the UGDP study coordinating center * * *; (3) neither the individual investigators nor the UGDP study coordinating center is an "agency" within the purview of the Freedom of Information Act, 5 U.S.C. § 552; and (4) consequently, the raw data in issue are not "agency records" subject to the disclosure provisions of the Freedom of Information Act * * *.

[12] The complaint also named Dr. Christian Klimt, director of the UGDP coordinating center at the University of Maryland School of Medicine, as a defendant (App. 5). As director, Dr. Klimt has actual possession of the data (App. 5, 180).

The court of appeals affirmed, concluding that the "public at large does not have a right under the Freedom of Information Act to the underlying raw data in the hands of the investigators and university groups who conducted the UGDP study program of diabetes under grants from the federal government" (App. 225-226). The court rejected petitioners' argument that the UGDP data are "agency records" because (i) the study that led to the data was entirely funded by the federal government, (ii) the data were available to the FDA and NIAMDD for copying and inspection, and (iii) the FDA had based regulatory decisions on the conclusions (although not on the underlying data) of the UGDP study.

Concerning the first factor, the court held that private grantees do not become federal agencies merely because they receive federal funds. Grantee autonomy persists despite the funding (App. 228-229, 233-235). Only where the government is involved "in the core planning or execution of the program," the court observed, may the recipient of a grant be considered a federal agency for purposes of the FOIA (App. 232 n.19 and 237). Concerning the second factor, the court noted that NIAMDD was not required to inspect and copy the data merely because it had a limited right to do so. A contrary rule, the court noted, would contravene the established principle that the FOIA does not oblige agencies to create records on request (App. 231-232).

Concerning the third factor, the court stressed that "need, interest or public interest" have no bearing on access under the FOIA (App. 226). If an agency were to rely on the conclusions of a private study whose underlying data it had not examined, the court suggested that the agency's action could be challenged as arbitrary, depending on the circumstances, under well-established mechanisms independent of FOIA (App. 226-227 n.11).

Judge MacKinnon concurred in the court's opinion, except for the portion suggesting that the Freedom of Information Act would apply not only to records in the possession of an agency but also to records the agency has a duty to obtain. As to records not in the possession of an agency, he stated, the application of the Act should be determined case-by-case (App. 238-239).

Judge Bazelon dissented. He noted that the federal government provided all funding for the UGDP study, the government has a right of access to the data, and the government had relied on the study and data in taking "regulatory action dealing with the treatment of diabetes" (App. 249). Under these circumstances, Judge Bazelon concluded that the "degree of federal involvement with the UGDP raw data" (App. 240) is sufficiently great that they should be treated as agency records for purposes of the FOIA.

INTRODUCTION AND SUMMARY OF ARGUMENT

Neither the Department of Health, Education, and Welfare, nor any of its relevant components—FDA, NIH and NIAMDD—has ever had ownership, custody or control of the UGDP patient data at issue in this case (App. 147, 180).[13] The records have at all times been owned and possessed by the UGDP coordinating center and its director, Dr. Klimt (App. 69, 180). The UGDP coordinating center is a private, non-government organization, not a federal agency. These conclusions are undisputed. In our view they are dispositive.

I.

The FOIA grants any person a right to inspect any reasonably identifiable nonexempt record in the custody and control of a federal agency. It establishes no right to inspect records owned by private individuals or groups and in their custody and control. This is clear from the plain language and structure of the Act and from its legislative history.[14]

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[13] The data copied by the FDA during its audit of UGDP have been provided to petitioners (App. 225). At issue here are only the data not copied by any federal agency and still in the exclusive possession of UGDP.

[14] A document is in the custody and control of an agency not only when the agency has possession of the document but also when the document is bailed or loaned to a private individual, another agency, or any other party who agrees to return it on request. Thus, an agency may not defeat FOIA disclosure by storing documents in a private warehouse rather than a federal records center (see App. 232 n.19).

Where, however, a document claimed to be an agency record is held by someone other than the agency under a claim of

A. The FOIA "makes available" to the public all nonexempt "agency records." 5 U.S.C. 552(a)(3). If "agency records" are improperly "withheld," the

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rightful possession, the agency is deprived of custody and control until the document is returned. In such circumstances, if a request is made to the agency for the missing materials, the agency does not "withhold" records within the meaning of the FOIA by not commencing legal proceedings for the return of the documents. This is true even if the agency arguably "owns" the documents or if they are arguably "records" under the Federal Records Act, 44 U.S.C. 3301, such that the agency is required to request the Attorney General to commence legal action to retrieve them (see 44 U.S.C. 3106). Thus, in *Kissinger* v. *Reporters Committee for Freedom of the Press*, Nos. 78-1088 and 78-1217, we argue that the Department of State did not "withhold" telephone notes made by Secretary Kissinger of his telephone conversations and donated by him to the Library of Congress before any FOIA request for them had been made merely because the State Department did not seek their return from the Library of Congress in order to satisfy the FOIA request. This is true even if the notes are "records" required to be preserved by the agency under Federal Records Act, 44 U.S.C. 2901 *et seq.* As Judges Leventhal and MacKinnon observed (App. 232 n.18, 238), however, the present case does not present any issue concerning an agency's duty under the FOIA to retrieve documents that it owns or that it is under a separate duty to obtain.

Although the issue is not presented by this case, in our view the requirement of "control" has force independent of the requirement of "custody." Thus, in *Goland* v. *CIA*, No. 76-1800 (D.C. Cir. May 28, 1978), pet. for cert. pending, No. 78-1924, we argue that where the House of Representatives loans an agency a transcript of an executive session hearing, stamps it "secret" and retains ownership and control of it, the transcript does not become an "agency record" under the FOIA merely because it is in the custody of the agency. The agency must also have sufficient control over the document to release it to the public. In *Goland* such authority has been exclusively retained by the House of Representatives.

complainant may sue to enjoin such "withholding." 5 U.S.C. 552(a)(4)(B). The Act does not define these terms, but their meaning is plain. "Agency records" means records of a federal agency. An agency does not "withhold" what it cannot produce —that is, what it does not have in its custody and control. If a document is outside the custody and control of a federal agency because, as here, it is owned and possessed by a private group, the FOIA does not require the agency to obtain and produce it for public inspection.

B. The legislative history reinforces this construction of the Act. The FOIA was provoked by a clearly delineated problem—prior law, principally Section 3(c) of the Administrative Procedure Act of 1946, 60 Stat. 238, gave federal agencies broad and unreviewable discretion to shield their documents from public view. Section 3 only required agencies to make available "matters of official record" to any person "properly and directly concerned" and permitted nondisclosure whenever, in the agency's view, "good cause" or "the public interest" demanded secrecy. By 1966, Congress concluded that these qualifications had led to widespread and unjustified withholding of requested agency documents. Abuse after abuse was cited in the legislative hearings and debates. Each was an example of an agency's refusal to divulge a record in its custody and control. To solve this problem, Congress in the FOIA prohibited "withholding" of "agency records" and replaced the agencies' discretion to withhold with nine specific exemptions. In

light of the discrete problem solved by the FOIA, the scope of the solution gathers precise meaning: non-exempt records in an agency's possession and control must be made available. The Act has no application to any other documents.

Other portions of the legislative history are consistent with this interpretation. The committee hearings and reports and the statements of individual legislators uniformly described the FOIA as comprehending "materials of the government," "executive branch records," "government documents" and materials "submitted to" or "controlled by" the government. Not once is there a suggestion that federal agencies would be obliged to procure and make available documents owned and possessed by private parties, regardless of the relationship between those documents and the government's business.

Indeed, the assumption that the Act comprehended only records in an agency's possession is made clearest in the comments of the agencies themselves. A number of agencies opposed passage of the FOIA, arguing chiefly that the law would impose a huge administrative burden in light of the volume of federal records and that retaining agency discretion to preserve secrecy on a case-by-case basis was wiser than enacting nine specific exemptions. If the agencies had ever imagined that these burdens would also extend to the billions of additional documents in the private sector that are "available" to an agency in reaching regulatory decisions or that have some nexus with public policy, they undoubtedly would have

voiced their objections loudly. The silence on this issue speaks volumes.

C. The structure of the FOIA also supports a limitation on its operation to documents in the custody and control of a federal agency. Several of the exemptions would make little sense if the Act applies to records outside an agency's possession. Exemption 4, for example, maintains the confidentiality only of trade secrets or commercial information "obtained from a person," while Exemption 8 preserves the secrecy of financial reports prepared by financial institutions "for the use of [a supervising] agency," without exempting the identical reports in the hands of the institutions themselves.

The procedural provisions of the Act convey the same interpretation. The stringent time limitations of 5 U.S.C. 552(a)(6) may be extended to allow an agency to consult with "another agency" interested in the disclosure of particular records. Agency employees may be punished by the court for contempt or disciplined for wrongful withholding of records, 5 U.S.C. 552(a)(4)(F), (G). No parallel authority is provided to allow consultation with private individuals or groups owning or possessing requested documents or to discipline private parties who thwart court orders to produce such documents. Obviously, such provisions were thought unnecessary because the Act was never intended to require the production of materials outside the custody and control of the government.

II.

The Court should reject petitioners' invitation to create an exception to the agency custody-and-control rule in this case because HEW (i) funded and "participated in" the design of the UGDP project, (ii) has access to the raw patient data for the purpose of auditing the project, and (iii) relied on reports of the UGDP study (but not the underlying data) for regulatory purposes. Individually and collectively, these factors do not warrant a deviation from the bright line drawn by Congress in defining what are "agency records" subject to the FOIA.

A. The fact that the UGDP project received federal funds cannot serve as a basis for applying the Act to the documents generated by that private group. In amending the definition of "agency" in 1974, Congress made clear that non-government organizations are not covered by the FOIA merely because they receive federal monies. H.R. Conf. Rep. No. 93-1380, 93d Cong., 2d Sess. 14-15 (1974). Nor does the agency's routine regulation and review of grantee activities make it a "partner" of the UGDP or deprive the grantee of exclusive ownership of the project's documents. HEW's oversight function here was limited to ensuring that a recipient of substantial federal funding was proceeding in a way designed to benefit the public interest. Moreover, HEW regulations state that title to grantee records vests in the grantee. 45 C.F.R. 74.132-74.133.

B. The UGDP documents are not "agency records" within the FOIA because the agency may have a right

of access to the documents under other statutes or regulations or under the terms of the grant. First, the agency's inspection rights are limited to specified purposes other than providing general access to the public. In addition, even if the agency were authorized to inspect and copy the raw patient data for reasons unrelated to the grant, such copying would not be required by the FOIA, which repeatedly has been held not to require the government to create records in response to requests. *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 161-162 (1975). Finally, there is hardly a document in the United States that is not subject to subpoena, summons or civil investigative demand. If agency access is a relevant criterion, the FOIA would reach large numbers of private materials related to public policy issues. Congress obviously intended no such result.

C. Nor does it matter that the agency relied on the reports and audits of the UGDP study for regulatory purposes. Every UGDP record actually considered by the agency in reaching its decisions has been fully disclosed. Petitioners want to see underlying data that even the agency has not seen. It goes without saying, however, that the FOIA does not create a right to know what even the government does not know. Even in its widest cast, the purpose of the Act was to disclose agency action and the materials viewed by the agency in taking that action. That purpose has been fully vindicated here.

D. Finally, the whole of petitioners' "congeries of considerations" (App. 230) is less than the sum of

its parts, for in its totality it transgresses Congress' fundamental purpose to eliminate the vague phrases that previously had governed agency disclosure and to replace them with a well-defined rule of complete disclosure of "agency records" subject only to nine discrete exemptions. Petitioners' approach, by relying on subjective factors such as "significant agency participation" and "agency reliance," reintroduces the very evil Congress sought to avoid in the FOIA. The bright line established by the Act—whether the documents are in the custody and control of a federal agency—is faithful to the statutory language and purpose, easy to apply and invites none of the controversy and litigation that would inevitably result from petitioners' balancing test.

ARGUMENT

The original patient records and related documents at issue in this case have at all times been owned and possessed by the private clinics conducting the UGDP study, by the UGDP coordinating center, and by the center's director, Dr. Klimt (App. 180). If UGDP were an "agency" under the Freedom of Information Act, then UGDP upon request would be required to make available to petitioners all nonexempt portions of its raw data. The FOIA, however, defines "agency" as "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C. 552(e). UGDP fits none of these descriptions.

The legislative history of the Act confirms that a private organization, even one receiving a federal financial assistance grant, is not an "agency." The Conference Committee Report on the 1974 amendments remarks (S. Conf. Rep. No. 93-1200, 93d Cong., 2d Sess. 14-15 (1974) (emphasis added)):

> The conferees state that they intend to include within the definition of "agency" those entities encompassed by 5 U.S.C. 551 and other entities including the United States Postal Service, the Postal Rate Commission, and government corporations or government-controlled corporations now in existence or which may be created in the future. *They do not intend to include corporations which receive appropriated funds but are neither chartered by the Federal Government nor controlled by it, such as the Corporation for Public Broadcasting.*

UGDP is not a "government controlled corporation." It receives federal monies, but that fact, as mentioned above, is not enough to make it an "agency" within the meaning of Section 552(e).[15] See *Ciba-*

[15] For purposes other than the FOIA, the receipt of federal funds has been held not to render an otherwise private organization a federal agency. See, *e.g.*, *Spark* v. *Catholic University*, 510 F.2d 1277 (D.C. Cir. 1975) (federal question jurisdiction); *Wahba* v. *New York University*, 492 F.2d 96 (2d Cir.), cert. denied, 419 U.S. 874 (1974) (applicability of constitutional limitations on discharge of employee working on grant-related project). See generally *United States* v. *Orleans*, 425 U.S. 807 (1976) (extent of liability of the United States

Geigy Corp. v. *Mathews*, 428 F. Supp. 523, 530 (S.D.N.Y. 1977).[16]

Significantly, petitioners do not contend that UGDP is a federal agency (see App. 255 & n.22). They instead rest their FOIA claim on the argument that the patient data are "records" of the Department of Health, Education, and Welfare, and that HEW must acquire the data from UGDP so that petitioners may examine them.[17] Petitioners urge (Br. 23-24) this

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under Federal Tort Claims Act for federal grantees' actions depends on whether day-to-day control exists).

[16] For decisions holding various private entities not to be "agencies" within the FOIA, see *Washington Research Project* v. *Department of HEW*, 504 F.2d 238, 248 (D.C. Cir. 1974), cert. denied, 421 U.S. 963 (1975) (peer review group advising a federal agency); *Ciccone* v. *Waterfront Com'n of New York Harbor*, 438 F. Supp. 55, 58 (S.D.N.Y. 1977) (Waterfront Commission of New York Harbor); *Lombardo* v. *Handler*, 397 F. Supp. 792, 793-795 (D.D.C. 1975), aff'd, 546 F.2d 1043 (D.C. Cir. 1976), cert. denied, 431 U.S. 932 (1977) (National Academy of Sciences); *Gates* v. *Schlesinger*, 366 F. Supp. 797 (D.D.C. 1973) (Defense Advisory Committee on Women in the Services); *Independent Investor Protective League* v. *New York Stock Exchange*, 367 F. Supp. 1376 (S.D.N.Y. 1973) (New York Stock Exchange). For a decision holding a government corporation to be an agency within the FOIA, see *Rocap* v. *Indiek*, 539 F.2d 174, 177 (D.C. Cir. 1976) (Federal Home Loan Mortgage Corporation).

[17] Actually, although petitioners frequently state that the data are 'agency records" (see Br. 23, 24, 25, 26, 27), they do not identify expressly the "agency" to which the records allegedly belong. Because petitioners sued officials of HEW, however, we assume that petitioners' references to "the government," "governmental access," "government direction and involvement" and similar generalized references refer to HEW or one of its component agencies.

result due to the confluence of three factors: (i) HEW was "significantly involved" in the design, implementation and policy direction and funding of the UGDP study, (ii) the agency enjoys a right of access to the data, and (iii) the agency has relied on the data for purposes of "regulatory decision making."

This argument fails for two reasons. First, the FOIA requires production only of records in the custody and control of a federal agency. It does not reach documents generated and held by private individuals, no matter how relevant those documents might be to the affairs of a federal agency. Second, considered both individually and in combination, the three factors identified by petitioners do not warrant the creation of an exception to the bright-line custody-and-control rule.

I. THE FOIA REQUIRES FEDERAL AGENCIES TO MAKE AVAILABLE ONLY RECORDS IN THEIR CUSTODY AND CONTROL

A. The Plain Language Of The Act Limits An Agency's Disclosure Obligations To Documents In Its Custody And Control

As this Court has repeatedly noted, the "starting point in every case involving the construction of a statute is the language itself." *Southeastern Community College* v. *Davis*, No. 78-711 (June 11, 1979), slip op. 6. The FOIA requires federal agencies to make all nonexempt "agency records" available for inspection by the public. It prohibits "withholding" of such records. If an agency improperly withholds a document subject to disclosure, the requester may

sue to enjoin the "withholding." 5 U.S.C. 552(a)(3), (a)(4)(B).

Congress found it unnecessary to define these terms more precisely because they plainly refer to documents in an agency's custody and control. "Agency records" obviously means records of a federal agency. "Withholding" cannot occur if the agency does not have the documents to produce. This is the interpretation of the Act adopted in the Attorney's General's contemporaneous memorandum explaining the provisions of the FOIA. *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967). And, it was the view of the Court in *NLRB* v. *Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978), describing the Act as reaching "records and material in the possession of federal agencies * * *." In short, the language of the Act plainly draws the line at documents in agencies' custody and control (see note 14, *supra*). As we now show, the legislative history and the overall structure of the FOIA also compel this conclusion.

B. The Legislative History Of The Act Confirms That An Agency Need Not Obtain Records From Private Organizations In Order To Satisfy An FOIA Request

No one would have been more surprised than the members of the 89th Congress to learn that the FOIA established a public right to review papers owned and possessed by private individuals. To be sure, the Act advanced significantly the public's right to learn of federal agencies' actions and of the materials considered by the agencies in taking those actions. The significant advances of the Act, however, were the

elimination of the previous rule that had permitted agencies broad and unreviewable discretion to withhold from public scrutiny records that unquestionably were in their custody and control and the establishment of an unqualified and enforceable right of "any person" (5 U.S.C. 552(a)(3)) to inspect all nonexempt and identifiable agency records. There is no evidence to suggest that the FOIA was ever intended to give the public a right to know information unknown to the government itself.

One of the surest guides in the interpretation of a statute is consideration of the particular mischief that Congress sought to prevent. See, *e.g.*, *Johansen* v. *United States*, 343 U.S. 427, 431 (1952); *Bindczyck* v. *Finucane*, 342 U.S. 76, 80-84 (1951). The scope of the FOIA gathers precise meaning in light of the specific defects in the public-disclosure procedures that led first to Section 3 of the Administrative Procedure Act of 1946, 5 U.S.C. (1964 ed.) 1002, and later to the FOIA in 1966. The "public information" section of the APA was provoked by mounting concern that administrative agencies had become an uncontrolled "fourth branch" of government. H.R. Rep. No. 1980, 79th Cong., 2d Sess. 2, 6-15 (1946). A major part of the problem—indeed, "an important and far-reaching defect in the field of administrative law"—was "a simple lack of adequate public information concerning its substance and procedure." *Id.* at 10-11. A House Committee investigating the matter reported that "[i]t is practically impossible for a Member of Congress, much less an individual citizen, to find his way among

these many agencies or to locate the particular officer or employee in any of the agencies with whom any particular problem should be discussed with a view to settlement." *Id.* at 9.

To solve this problem, Section 3 of the APA imposed on federal agencies the duty to publish information concerning their organization, procedures, substantive rules, opinions and orders.[18] In addition, in order "to make access to public records generally applicable, uniform, and more readily determinable" (H.R. Rep. No. 1980, *supra*, at 23),[19] Section 3(c) required that certain "matters of official record" be made available to persons with a "need to know" (60 Stat. 238):

> Except to the extent that there is involved (1) any function of the United States requiring secrecy in the public interest or (2) any matter relating solely to the internal management of an agency—
>
> * * * * *
>
> (c) * * * Save as otherwise required by statute, matters of official record shall in accordance with published rule be made available to persons properly and directly concerned except information held confidential for good cause found.

[18] The overriding purpose of Section 3 was to inform "the general public" about procedures and methods" (H.R. Rep. No. 1980, *supra*, at 21) and "to assist the public in dealing with administrative agencies by requiring agencies to make their administrative materials available in precise and current form." *Attorney General's Manual on the Administrative Procedure Act* 17 (1947). It was "drawn upon the theory that administrative operations and procedures are public property which the general public, rather than a few specialists or lobbyists, is entitled to know * * *." H.R. Rep. No. 1980, *supra*, at 25.

[19] Accord, S. Rep. No. 752, 79th Cong., 1st Sess. 1-4, 6, 12-13 (1945).

Section 3(c) applied, however, only to documents in the custody of an agency; indeed, it applied only to matters of "official record." In 1947, the Attorney General advised federal agencies that "official records" included materials such as "applications, registrations, petitions, reports and returns filed by members of the public with the agency pursuant to statute or the agency's rules" and "all * * * documents embodying agency actions, such as orders, rules and licenses." *Attorney General's Manual on the Administrative Procedure Act* 24-25 (1947). As examples of "official records," the Attorney General's Manual cited "[m]aps, plats or diagrams in the custody of the Secretary of the Interior," "records, books or papers in the General Land Office," "registration statements filed with the Securities and Exchange Commission," and pleadings, transcripts of testimony, exhibits, and all documents received in evidence or made part of the record in official proceedings. *Ibid.* The manual stated, however, that the "great mass of material relating to the internal inspection of an agency is not a matter of official record." *Id.* at 25. One type of document not subject to disclosure was "intra-agency memoranda" prepared for use within the agency. *Ibid.*

Nothing in the language or legislative history of Section 3(c) of the APA, in the Attorney General's Manual, or in the cases decided under that section offers the slightest hint that the statute was designed

to confer on the public a right to inspect documents in the hands of government grantees, contractors or other private persons. The problem addressed by Section 3(c) was far more basic. For the first time, it established a right of "directly concerned" individuals to inspect "official records," such as orders or other evidence of actions taken by an agency and the materials relied on by the agency, except where "good cause" or the "public interest" required secrecy.

Although Section 3 of the APA was a substantial improvement over prior law, the section was generally recognized as falling far short of its disclosure goals and came to be looked upon more as a withholding statute than a disclosure statute. See *EPA* v. *Mink*, 410 U.S. 73, 79 (1973). The qualifications in Section 3(c) invited abuse, and by 1966 Congress concluded that the section was "full of loopholes which allow agencies to deny legitimate information to the public." S. Rep. No. 813, 89th Cong., 1st Sess. 3 (1965) (Senate Rep.). Specifically, four defects were found (*id.* at 5):

> (1) There is excepted from the operation of the whole section "any function of the United States requiring secrecy in the public interest * * *." There is no attempt in the bill or its legislative history to delimit "in the public interest," and there is no authority granted for any review of the use of this vague phrase by Federal officials who wish to withhold information.

> (2) Although subsection (b) requires the agency to make available to public inspection "all final opinions or orders in the adjudication of cases," it vitiates this command by adding the following limitation: "* * * except those required for good cause to be held confidential * * *."
>
> (3) As to public records generally, subsection (c) requires their availability "to persons properly and directly concerned except information held confidential for good cause found." This is a double-barreled loophole because not only is there a vague phrase "for good cause found," there is also a further excuse for withholding if persons are not "properly and directly concerned."
>
> (4) There is no remedy in case of wrongful withholding of information from citizens by Government officials.

As a result of these deficiencies, the Senate Report noted, agency officials had actually turned the statute on its head by using it as an excuse to withhold information (Senate Rep. at 5). The Freedom of Information Act sought to close these loopholes by making three "major changes" (Senate Rep. at 5-6):

> (1) It sets up workable standards for what records should and should not be open to public inspection. In particular, it avoids the use of such vague phrases as "good cause found" and replaces them with specific and limited types of information that may be withheld.
>
> (2) It eliminates the test of who shall have the right to different information. For the great majority of different records, the public as a whole has a right to know what its Government

> is doing. There is, of course, a certain need for confidentiality in some aspects of Government operations and these are protected specifically; but outside these limited areas, all citizens have a right to know.
>
> (3) The revised section 3 gives to any aggrieved citizen a remedy in court.

Hence, the FOIA makes available "to any person" all identifiable agency documents, which it divides into three categories: some must be published in the *Federal Register* (5 U.S.C. 552(a)(1)); others must be published or made publicly available and indexed (5 U.S.C. 552(a)(2)); and all others must be furnished on request (5 U.S.C. 552(a)(3)). The FOIA then defines nine categories of documents to which the Act "does not apply" (5 U.S.C. 552(b)). Finally, the district courts are given "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant" (5 U.S.C. 552(a)(4)(B)).

Three points emerge from this brief discussion to support the conclusion that the FOIA extended the duty to disclose only to "agency" documents in the custody and control of a federal agency. First, Congress identified with precision the failing in the APA "public information" section—agencies were withholding documents in their possession for invalid reasons or for no reason at all. Examples of the abuses noted by Congress included the withholding of agency telephone directories (H.R. Rep. No. 1497, 89th Cong., 2d Sess. 5 (1966) (House Rep.)), the names, positions and salaries of agency employees, cost estimates submitted by unsuccessful contractors to the National Science Foundation, dissents of members of regulatory commissions from official agency actions, and a proposed spending program for an agency (House Rep. at 6). Every example mentioned in the legislative debates and reports was of a document in the unquestioned custody and control of a federal agency.

In response to the "withholding" problem, Congress made clear that the duty to disclose applied to all "agency" records, not just those that the agency deemed "official" or "public," [20] subject only to nine discrete exemptions. But Congress did not criticize, much less alter, the prior rule that agencies did not have to obtain and make available any documents in private hands.[21] Section 3(c) plainly did not extend that far, but the limitation was of no concern. The term "agency records" in the FOIA must therefore be construed in view of the specific problem Congress did seek to remedy—an agency's refusal to divulge nonexempt records in its possession.

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[20] Section 3(c) of the APA was entitled "public records" and required "matters of official record" to be made available, subject to the qualifications discussed above. The FOIA used the phrase "agency records" to eliminate any inference that agencies could avoid disclosure of "nonpublic" or "unofficial" files in their custody. See Senate Rep. at 7.

[21] In subsequent years Congress identified additional deficiencies in the FOIA, but not once has it ever suggested that production of grantee or other private records is an objective of the Act. See generally H.R. Rep. No. 92-1419, 92d Cong., 2d Sess. (1972); S. Rep. No. 93-854, 93d Cong., 2d Sess. (1974) (1974 Sen. Rep.); H.R. Rep. No. 93-876, 93d Cong., 2d Sess. 1974) (1974 House Rep.).

Second, in describing how the FOIA would operate, the comments of congressional committees and individual legislators consistently limited the scope of disclosure to documents in the government's custody and control. Thus, the committee reports observed that under FOIA "all [nonexempt] *materials of the Government* are to be made available" (Senate Rep. at 10; House Rep. at 11 (emphasis added)) and that the Act "would * * * provide a true Federal public records statute by requiring the availability * * * of all of the *executive branch records* * * *" (House Rep. at 1 (emphasis added)). Each request must contain a "reasonable description enabling *the Government employee* to locate the requested records" (Senate Rep. at 8; House Rep. at 9 (emphasis added)).[22] Certain confidential data "*submitted* * * * to a lending agency," "*obtained by* the Government," "*collected* by Government agencies," or *filed* with Federal agencies," otherwise subject to disclosure, were made exempt (Senate Rep. at 9; House Rep. at 10-11 (emphasis added)).

Individual comments by legislators and agencies echoed this understanding. Representative Moss, a sponsor of the FOIA, remarked that the law gave legal recognition to the public's "basic right to gain

[22] Similarly, when Congress modified this provision in 1974, the House Report stated that "[a] 'description' of a requested document would be sufficient if it enabled *a professional employee of the agency* who was familiar with the subject area of the request to locate the record with a reasonable amount of effort." 1974 House Rep. at 6. See also 1974 Senate Report at 10, 24, 25.

access" to "official records" and "public records" 112 Cong. Rec. 13641-13642 (1966). Other legislators noted that under the FOIA records "of official government action [] are public property," [23] that agencies must disclose "all their records" not exempted so that citizens would "have a right to obtain public records * * *," [24] and that the Act concerned "public records." [25]

Moreover, during the Senate hearings on the FOIA a representative of the Interstate Commerce Commission commented that "[s]ince the word 'records' * * * is not defined, we assume that it includes all papers which an agency preserves in the performance of its functions." *Administrative Procedure Act: Hearings on S. 1160, S. 1336, S. 1758, and S. 1879 Before the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 89th Cong., 1st Sess. 244 (1965) (1965 Senate Hearings).[26] The Comptroller General suggested that all documents produced under the FOIA should "remain" in the custody of the agency. *Id.* at 376. And at the close of the House hearings, Senator Ervin observed that in the final measure "every legitimate need for protection of any record or information *in the custody of departments or agencies* has been considered in

[23] 112 Cong. Rec. 13653 (1966) (Rep. Rumsfeld).

[24] 112 Cong. Rec. 13660 (1966) (Rep. Dwyer).

[25] 112 Cong. Rec. 13657 (1966) (Rep. Reid).

[26] This appears to be the only statement in the legislative history of the FOIA attempting to define the term "records" or "agency records."

the House and Senate measures." *Federal Public Records Law: Hearings on H.R. 5012 et al. Before a Subcomm. of the Comm. on Government Operations*, 89th Cong., 1st Sess. 166 (1965) (1965 House Hearings).[27] Not once, so far as we are able to determine, is there a suggestion in any of the congressional hearings, reports, or floor debates that the Act might reach privately owned and possessed materials, regardless of the relationship between those materials and governmental functions.

This legislative silence speaks volumes. Both the House and Senate Committees asked all federal agencies to comment on the proposed FOIA, and many did. 1965 House Hearings at 203-276; 1965 Senate Hearings at 365-505. Almost without exception, federal agencies opposed mandatory disclosure of all nonexempt documents, chiefly on the grounds that mandatory disclosure would impose a huge administrative burden in view of the large number of agency records[28] and that depriving agencies of all discretion to withhold was unwise.[29] Agency opponents of the FOIA cited numerous examples of unreasonable disclosures that would be required by the bill.[30] It is significant that none of these examples involved documents not in the custody and control of the federal government. Had it been imagined by anyone that the administrative burdens to be imposed by the Act would also extend to acquiring and producing documents in the private sector, even if limited to records of federal grantees or other private individuals or groups dealing with the government, the objections to the bill unquestionably would have multiplied. The "awesome implications" (App. 234) of disclosure of billions of private documents could not have gone unnoticed. Obviously, proponents and opponents of the FOIA alike assumed that the Act reached only the records in the possession and control of federal agencies.

Our discussion would not be fair if we did not acknowledge that the issue presented in this case was not a central focus of Congress in considering the FOIA. But we believe it is of immense probative value that the isolated comments that do appear in the legislative history consistently favor the view we espouse. Perhaps even more noteworthy, there is not a single comment in the legislative history to lend weight to petitioners' tortured reading of the Act. In sum, in the face of such silence concerning a bill as much debated as the FOIA, "[i]t would require the suspension of disbelief to ascribe to Congress the design to" require the release of records in private hands. *Brown* v. *GSA*, 425 U.S. 820, 833 (1976); see

[27] In keeping with this original understanding, a House oversight study in 1972 characterized the FOIA as a "promise of access to public records." H.R. Rep. No. 92-1419, 92d Cong., 2d Sess. 9 (1972).

[28] See, *e.g.*, 1965 Senate Hearings at 204, 236, 244, 382, 483. Professor Davis suggested that the burden would be enormous but could be mitigated by giving agencies time to establish two records systems—one open to public perusal and one closed to the public. 1965 Senate Hearings at 147-158.

[29] See, *e.g.*, 1965 Senate Hearings at 366, 376, 383, 402, 406, 416-419, 425, 436, 440, 445, 470, 489.

[30] See, *e.g.*, 1965 Senate Hearings at 196, 479.

Edmonds v. *Cumpagnie Generale Transantlantique*, No. 78-479 (June 27, 1979) slip op. 9-10.

C. The Structure Of The Act Reinforces The Conclusion Offered By Its Language And Legislative History

This Court has often looked to the complete structure of a statute to illuminate the meaning of its parts. *Train* v. *NRDC*, 421 U.S. 60, 86 (1975); *SEC* v. *Sloan*, 436 U.S. 103, 121 (1978); *Miller* v. *Youakim*, No. 77-742 (Feb. 22, 1979), slip op. 12-13; *Alexander* v. *HUD*, No. 77-874 (Apr. 17, 1979), slip op. 19; *So. Ry. Co.* v. *Seaboard Allied Milling Corp.*, No. 78-575 (June 11, 1979), slip op. 11. The structure of the FOIA reveals at virtually every turn an intent to reach only documents in the custody and control of a federal agency.

First, the term "agency records" gains content when viewed against the types of agency records exempted from disclosure. Section 552(b)(4), for example, exempts trade secrets and commercial or financial information "obtained from a person," without making any provision for the identical information in the possession of a federal grantee or other private party. Exemption 4 was meant to protect confidential information "submitted" by a borrower to a lending agency or "obtained by the Government" through questionnaires or other inquiries, where such information "would customarily not be released to the public by the person from whom it was obtained." Senate Rep. at 9; House Rep. at 10. That Congress found it necessary to exempt only such materials in the possession of an agency demonstrates that, a

priori, the Act has no application to similar documents in private hands, regardless of the connection between those documents and the agency's official functions. Until the agency has actually "obtained" the records, Exemption 4 (and, logically, the FOIA itself) are inapplicable.

By the same token, Section 552(b)(8) exempts certain reports "prepared * * * for the use of an agency responsible for the regulation or supervision of financial institutions." The Act does not exempt similar financial information prepared for the use of and held by the financial institutions themselves. Congress, however, clearly intended that such information would be made "available only to the Government agencies responsible for the regulation or supervision of such institutions" (Senate Rep. at 10; House Rep. at 11). Obviously, then, Congress did not intend the FOIA to reach those private documents.

The procedural provisions of the Act tell the same story. Agencies normally must decide within 10 days whether to comply with an FOIA request, but they may extend the time to 20 days where there is a need to consult with "another agency having a substantial interest in the determination of the request." 5 U.S.C. 552(a)(6)(B)(iii). See H.R. Conf. Rep. No. 93-1380, 93d Cong., 2d Sess. 11 (1974). Had Congress contemplated that documents owned and possessed by private parties were subject to disclosure, it undoubtedly would have allowed an extension of time for consultation with such private parties, not just with other federal agencies.

Similarly, Section 552(a)(4)(B) authorizes district courts to enjoin any "agency" from "withholding" records and places the "burden * * * on the agency to sustain its action." No provision is made for enjoining private individuals or groups from withholding their own records or for placing the burden on them to justify the refusal to relase. Section 552(a)(4)(G) empowers the court to punish for contempt any responsible agency employee who violates an order to produce withheld documents, and Section 552(a)(4)(F) requires the Office of Special Counsel of the Merit Systems Protection Board to consider whether disciplinary action is warranted against any federal employee who, in the court's view, arbitrarily withholds agency records (see Civil Service Reform Act of 1978, Pub. L. No. 95-454, Section 202(a), 92 Stat. 1121, 1128, adding 5 U.S.C. 1206 (e)(1)(C)). No analogous authority is provided to punish private parties for similar acts. See generally 1974 Senate Rep. at 21-24; H.R. Conf. Rep. No. 93-1380, *supra*, 10. Again, had Congress intended the FOIA to reach documents in private hands, it surely would not have omitted parallel enforcement provisions designed to prevent non-government individuals from frustrating a disclosure order. The omission demonstrates quite clearly that Congress meant to limit the universe of records covered by the Act to those in the custody and control of a federal agency.

II. THE FOIA SHOULD NOT BE EXTENDED BY IMPLICATION TO REACH THE UGDP DOCUMENTS AT ISSUE IN THIS CASE

The FOIA would be a remarkable statute indeed if it required private parties to open their papers to the public at large. Petitioners do not urge such a broad reading of the Act; in any event, such a contention (in light of the evidence mentioned above) would be untenable. Rather, petitioners argue (Br. 23-25) that a "limited" extension of the Act to cover the UGDP raw patient data would further the policies of the FOIA because (i) HEW "participated" in the design of the UGDP study and funded it, (ii) the agency has a right of access to the pertinent data, and (iii) the agency has relied on the data in making regulatory decisions.[31]

There are two problems with petitioners' approach. First, unless the exception carved into the FOIA at petitioners' behest were to be confined to the UGDP documents alone, it would be difficult if not impossible to identify limiting criteria in order to prevent billions of other private documents from falling within the disclosure requirements of the Act. Petitioners have mentioned three factors that they believe make the private records in this case sufficiently "federal"

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[31] Actually, only the NIAMDD funded the UGDP project and reviewed the project design and only the FDA proposed to regulate oral hypoglycemic drugs. NIAMDD and FDA are the same agency only in the sense that they are both components of HEW, which is an "agency" under 5 U.S.C. 552(e). For purposes of argument, however, we assume that a single agency has performed the acts or has the powers set forth in petitioners' "congeries of considerations" (App. 230).

to mandate release under the statute. But some of these factors would apply equally to virtually every meaningful document in the hands of a private group receiving federal funds. While others would not, future requesters could identify additional factors, not present here, in order to "federalize" the private records to which they seek access under the Act.

Moreover, as we discuss in more detail below, the three factors on which petitioners rely, considered individually and collectively, do not warrant an extension of the FOIA to include the UGDP documents, which are not in the possession, custody or control of a federal agency.

A. Agency Funding And Review Of The UGDP Project

Petitioners contend (Br. 28-36) that HEW's funding and auditing of the UGDP project and its participation in the project's design transforms the UGDP data into "agency records." But, as we have already noted (see pages 20-23, *supra*), UGDP is not a federal agency within the meaning of the FOIA. Congress expressly elected not to subject recipients of federal funds to the disclosure requirements of the Act. The fact that UGDP has received federal funding, therefore, is immaterial to the question presented in this case.

Moreover, the agency's regulation of grantees does not make the relationship a "partnership" whose documents belong to the agency. No doubt, Congress could provide that all property acquired by federally financed projects belongs to the United States. It has not done so. To the contrary, the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-

224, Section 4, 92 Stat. 4, requires agencies to use "procurement contracts" when the "principal purpose of the instrument is the acquisition * * * of property or services for the direct benefit or use of the Federal Government * * *." In contrast, "grant agreements" must be used when money is given to a recipient "in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition * * * of property or services * * *" (Section 5, 92 Stat. 4). Here, a grant was used because there was no intent to acquire property.[32]

Indeed, the regulations governing the administration of HEW funding programs specifically provide that "title to real property, equipment, and supplies acquired under a grant or subgrant shall vest, upon acquisition, in the grantee or subgrantee respectively." 45 C.F.R. 74.133. The materials constituting the original UGDP patient records and related forms are "supplies" within the meaning of this provision. 45 C.F.R. 74.132.[33] To be sure, at the end of certain projects, HEW may require a grantee to transfer title to certain property to the agency. See 45 C.F.R. 74.135-74.136. That, however, has not happened here and will not under present regulations.[34] In short,

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[32] The specific UGDP grants do not retain for the government ownership of materials accumulated by the recipients.

[33] "Supplies" means "all tangible personal property other than equipment." "Personal property" means "property of any kind except real property." 45 C.F.R. 74.132.

[34] Section 7(b) of the Federal Grant and Cooperative Agreement Act empowers agencies to permit grantees who are "nonprofit institutions of higher education" or "nonprofit organizations" engaged in "scientific research," as here (see App. 220 n.3), to retain "title to equipment or other tangible

ownership of the data in question is now (and shall remain) in the UGDP. It is not "partnership" property.[35]

That UGDP owns the data is no accident. It is the result of a conscious policy distinction between grants and procurement contracts. When the government

personal property purchased with such funds." 92 Stat. 5. 45 C.F.R. 74.135(c) implements this statute by providing that title to "supplies" in such cases will remain in the grantee.

[35] Petitioners assert (Br. 29) that under 45 C.F.R. 74.24 "[t]he public at large has its own rights of access to grantee records, which can be restricted only in special and limited circumstances." If that were so, this FOIA lawsuit would never have been necessary. It is not so, however. Section 74.24 only provides for access by "HEW and the Comptroller General of the United States, or any of their authorized representatives * * *." Section 74.25, which may have been the subject of petitioners' observation, likewise offers no aid to petitioners. It provides:

> Unless required by Federal statutes, awarding parties may not impose grant or subgrant terms which limit public access to records covered by this subpart except after a determination by the granting agency that the records must be kept confidential and would have been excepted from disclosure under HEW's "Freedom of Information" regulation (Part 5 of this title) if the records had belonged to HEW. This section does not require recipients or their contractors and subcontractors to permit public access to their records.

This provision merely prohibits agencies or grantees from restraining a recipient or subgrantee who desires to allow public access to his records. It specifically disclaims any intent to require public access to the records. Finally, needless to say, the regulations cited by petitioners (Br. 29) governing public use of government-owned or financed inventions (45 C.F.R. 6.1, 8.0) have no applicability to the UGDP patient records.

wishes to buy services or goods, it uses a procurement contract, as directed by tradition and the 1977 Act. See Mason, *Current Trends In Federal Grant Law—Fiscal Year 1976*, 35 Fed. Bar. J. 163, 166-168 (1976); Staats, *Federal Research Grants*, 205 Science 18, 19 (July 6, 1979). When the government wishes to promote certain nongovernmental activity in order to promote the public interest, it uses a grant, as required by tradition and the 1977 Act. The grantee may use the funds of the grant as his own (within the terms of the grant), and the property he acquires during the grant is his own, subject only to whatever accounting must be made at the end of the project.

Nor does it matter that NIAMDD "participated" in the design of the UGDP project and monitored it for compliance. So far as the record discloses (see generally App. 145-148), NIAMDD did no more than would be expected of any federal agency in ensuring that a project run by private persons with federal funds was structured and implemented so as to be sufficiently in the public interest to deserve initial and continued funding.[36] As the court of appeals observed, there was no "significant government control of day-by-day operation [of the UGDP program], or detailed involvement in the planning or execution

[36] See *United States* v. *Orleans*, 425 U.S. 807, 815-816 (1976) (footnote omitted): "[B]illions of dollars of federal money are spent each year on projects performed by people and institutions which contract with the Government. These contractors act for and are paid by the United States. They are responsible to the United States for compliance with the specifications of a contract or grant, but they are largely free to select the means of its implementation."

of the program, [so] the overall concept of autonomy of grantees persists, even though there are federal objectives, right of federal audit and perhaps some over-arching federal requirements" (App. 237).

Finally, a rule requiring disclosure in these circumstances would impose new and serious burdens on acceptance of a federal grant. Grantees would be forced to accept the obligations not only to perform adequately and to comply with the various record-keeping, reporting and audit requirements that accompany a grant, but also to suffer disclosure to any member of the public of all documents related to the project funded by the grant if the "government participation" test is met. Organizations unwilling to subject their projects to such unlimited public scrutiny might well forego federal funding, with the consequent harm both to the private organization and to society in general (see App. 235-236).[37] Perhaps equally as troubling, federal agencies might be encouraged to reduce scrutiny of their grantees' projects in order to avoid a charge of "significant involvement in the study's planning, implementation, and monitoring" (see Pet. Br. 28). This, too, would obviously work to the detriment of the grantee and the public interest.[38]

[37] This problem is discussed in more detail in the Brief of the American Council on Education, et al., as Amici Curiae.

[38] As petitioners frankly concede (Br. 30), "NIH could choose to establish a different type of partnership structure providing less (or more) grantee accountability or autonomy. Similarly, would-be grantees could decide that the benefits of NIH funding are outweighed by the costs of NIH control and therefore decline involvement in the extramural program."

In sum, NIAMDD's funding, "participation" and regulation of the UGDP project do not overcome the undeniable fact that UGDP alone owns and possesses the raw patient data. Insofar as the FOIA is concerned, petitioners are no more entitled to inspect the UGDP records on account of the federal funding and "participation" than they would be to inspect data developed by similar private research programs receiving no federal assistance at all.

B. Agency Access To The Project Data

Petitioners argue (Br. 37-42) that HEW's right of access to private grantee records under its regulations establishes their right to the same records under the FOIA. There are a number of flaws in this reasoning. The first was noted by Judge Leventhal, writing for the court below: To the extent that language in these regulations, or in the UGDP grant itself, gives HEW a right of access to the UGDP records, "it indicates that these are not agency records prior to the exercise of that right" (App. 231).

Moreover, petitioners ignore the fact that NIAMDD's right of access is limited to specified regulatory purposes. 45 C.F.R. 74.24 authorizes the granting agency to inspect UGDP's records only "in order to make audit, examination, excerpts, and transcripts." 21 C.F.R. 312.1 authorizes the FDA to inspect the UGDP patient data only for reasons related to the investigational new drug exemptions

obtained by the private group. Neither of these provisions authorizes, much less requires, the agency to seek access to the data for the sole purpose of allowing the public at large to rummage through UGDP's records.

This problem may not be solved by requiring the agency to copy the 55 million documents and hold the copies for public inspection. Such a course would be a subterfuge without any more anchor in the agency's inspection authority than allowing the public to inspect the original data. In any event, imposition of that obligation on the agency would contravene the established principle that the FOIA does not require the government to generate records for the purpose of public disclosure. *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 161-162 (1975); *Renegotiation Board* v. *Grumman Aircraft Engineering Corp.*, 421 U.S. 168, 192 (1975); *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967).[39]

Indeed, the suggestion that a federal agency's right of access to private documents for regulatory pur-

[39] A separate problem with petitioners' argument is that it would imply into the FOIA a private right of action to force an agency to exercise its option to obtain a record it does not but could possess. We have discussed this issue in the government's brief in *Kissinger* v. *Reporters Committee for Freedom of the Press*, Nos. 78-1088 and 78-1217 (pages 34-38). Here, the case for an implied private right of action is even weaker than in *Kissinger* because the authority creating the right of access is a regulation, not a statute, and is permissive, not mandatory.

poses somehow requires the agency to obtain the record in response to an FOIA request falls of its own weight. "Right of access" provisions are common in federal grants and contracts. See *Eli Lilly & Co.* v. *Staats*, 574 F.2d 904 (7th Cir.), cert. denied, No. 78-190 (Nov. 6, 1978). Beyond that, there is hardly a document in the United States that is not subject to subpoena, summons or civil investigative demand.[40] It is not an overstatement to say that federal agencies have a right of access to many documents in the hands of almost everyone who deals with the federal government, and almost everyone deals with the federal government. In short, the fact that a federal agency may have the right to inspect private documents for specified purposes related to the agency's statutory goals does not establish a derivative FOIA right of the public to do the same.

C. Agency Reliance On The UGDP Study

Petitioners' final contention (Br. 43-50) is that the data at issue in this case should be disclosable under the FOIA because the FDA has taken regulatory action based in part on the published results of the UGDP study. "[T]his absorption of the raw data into the regulatory process," petitioners assert,

[40] It is no answer to this argument to say that the government would never be required to subpoena a document solely for FOIA purposes because that would be a misuse of the subpoena power. It would be an identical misuse of the government's access rights under a regulation, contract, or grant for an agency to obtain records for the sole purpose of complying with an FOIA request.

"inextricably renders them 'agency records'" (*id.* at 43). But the fact that the agency may have relied on the reports and audits of the project does not transform the underlying patient data into "agency records." Even in its broadest cast, the purpose of the FOIA is to inform the public of the "decisions their government is making" and "the basis on which those decisions are being made." S. Rep. No. 93-854, 93d Cong., 2d Sess. 5 (1974). It does not create a right to know what even the government does not know.

Here, the decisions of the FDA concerning oral hypoglycemic drugs and the bases of those decisions —the reports and audits—have been fully disclosed to petitioners and the public (see page 13, note 13, *supra*). The agency informed petitioners on a number of occasions that "this Department does not now have and never has had any of the raw data on which the UGDP study was based" (App. 57). If the agency's decision not to review all 55 million UGDP documents was a mistake or an abuse of discretion, the full force of the FOIA has been spent in bringing that mistake to the public's attention. As the court of appeals noted (App. 226-227 n.11), the agency's substantive regulatory decision may be challenged "by well-established mechanisms independent of FOIA." See 5 U.S.C. 706; *Renegotiation Board* v. *Bannercraft Clothing Co.*, 415 U.S. 1, 24 (1974).

Petitioners' position in this regard is not enhanced by their extended explanation of why they need the original patient data (Br. 34-36, 50-52). Need is not a relevant factor under the Act. See Davis, *Administrative Law Treatise* § 3A.21 (1970 Supp.). The FOIA confers a right of access on the general public to all nonexempt agency records. The universe of documents comprehended by the Act is neither diminished nor enlarged by the reason the request is made. *NLRB* v. *Sears, Roebuck & Co.*, *supra*, 421 U.S. at 143 n.10. Hence, the fact that the UGDP "study is not replicable" (Pet. Br. 36) and that petitioners must receive the raw data if they are to validate or disprove the study's findings is entitled to no weight in this litigation. If petitioners' legal arguments are correct, then *any* requester would be equally entitled to inspect the records for any purpose or for no purpose at all.

Finally, petitioners' reading of the FOIA, if accepted, would severely hamper federal agencies, especially in the health area, by effectively requiring every agency that relies on a scientific study in taking agency action to acquire and make available the often voluminous underlying data used in the study. Agencies often rely on published medical and scientific studies in rulemaking and enjoy wide discretion in determining how much supporting data to obtain (see App. 227 n.12).[41] Petitioners' interpretation of the Act would rob agencies of much of this discretion.

Indeed, petitioners' argument presumably would impose the same burden where the agency declines to

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[41] See *FCC* v. *Pottsville Broadcasting Co.*, 309 U.S. 134, 143 (1940); *Wisconsin* v. *FPC*, 373 U.S. 294, 313-314 (1963); *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 786 n.2, 791-792 (1969); *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 524-525 (1978).

regulate. An agency may receive a study urging stricter regulation but may discount its methodology and significance in the face of professional criticisms and decide not to follow its conclusions. Under petitioners' analysis, the agency would be dutybound to obtain and make available the raw data of the study so that proponents of regulation could answer the critics. The government, in sum, would be prevented from relying on the vast wealth of professional findings in the public domain except in the most compelling cases where the need justified the trouble and expense of reviewing the underlying data.[42] There

[42] Even if petitioners' rule were limited to federally-funded projects, it would affect a large sector of public health research in the United States. Federal health research grants alone totalled approximately $4 billion in fiscal year 1978. See Brief of the American Council on Education, et al. as Amici Curiae at 4. In the same year, the United States spent $26 billion in research and development grants. *Id.* at 20. Government agencies currently fund approximately 16,000 research grants. *Id.* at 21.

The burden on the government of obtaining, copying, storing, and making available for disclosure raw data in cases like this one would be enormous. The UGDP study, involving approximately 1,000 patients and some 55 million documents as raw data, is not the largest such study ever undertaken by a private group with federal funding. For example, the Framingham Epidemiological Study of Cardiovascular Disease, funded by grants from the National Heart Institute, a component of NIH, has been underway since 1949 and involves over 5,000 patients. See, *e.g.*, Gordan & Kannel, *Predisposition to Atherosclerosis in the Head, Heart and Legs; The Framingham Study*, 221 J.A.M.A. 661-666 (1972). The Coronary Drug Project, funded by the National Heart and Lung Institute, another component of NIH, has been underway since 1969 and involves over 8,000 patients being treated in 53 clinics. Unlike the UGDP, the inspiration for this study came from the Institute's Advisory Heart Council. *The Coronary Drug Project*, Circulation, Vol. XLVII, No. 3, (Supp. No. 1, March, 1973). The volume of raw data in these studies will far exceed that in the UGDP. Yet, these are only two of over 1,800 studies currently funded by NIH. Additional studies are funded by the Department of Energy, the Department of Labor and other federal agencies.

may well be strong arguments in favor of this change in agency decisionmaking, but those arguments should be adopted, if at all, as a matter of administrative law, not FOIA policy.

D. The Combination Of Factors Identified By Petitioners Does Not Justify Treatment Of The UGDP Data As Agency Records

The "congeries of considerations" (App. 230) offered by petitioners is even less compelling than its parts. To begin with, each factor still suffers in combination the same faults it suffers individually. More important, however, petitioners' argument, by predicating FOIA relief on an amalgam of variables, introduces a vague and unworkable test into the FOIA. Release of records not in the agency's possession and control would turn on the substantiality of the agency's "involvement" in the production of the records, the scope of its "access" rights, the degree of its "reliance" on the report prepared by use of the records, and perhaps even whether the records are "unique" or "non-replicable" (Pet. Br. 25). Depending on the force of these factors in each case, millions or even billions of private documents would be deemed "agency records." Such an amorphous test, "based

upon all of the circumstances of the given case" (Pet. Br. 27), flies in the face of the congressional intent to eliminate the "vague phrases" in the APA and to replace them with "workable standards for what records should and should not be open to public inspection." Senate Rep. at 5; House Rep. at 5-7. See pages 28-29, *supra*. Petitioners' elastic standards reintroduce the very evil Congress sought to avoid.

In addition, as noted earlier (see page 39), there is no principled way to limit the definition of "agency records" to the factors petitioners have relied on here. Petitioners have obviously focused on the particular indicia of federal agency involvement in or connection with the UGDP data in an effort to win *this* case. But the next case to raise the issue may involve slightly different indicia—for example, the experiments that led to the raw data may have been performed by a private group in a government-leased laboratory, or a grantee may have been hired by a federal agency following his study in order to advise the agency on his findings. A host of other possibilities could easily be imagined. Nothing in the FOIA or its legislative history gives any hint as to how the judiciary would tackle the problem of deciding how much weight to give to each of these factors.

Congress' plan to establish a bright line between what is and is not subject to disclosure is of substantial importance in the administration of the FOIA. The bright line adopted in the Act—that only documents in the custody and control of a federal agency are subject to disclosure—has worked well in

practice and is vitally important in the prompt and accurate processing of thousands of FOIA requests annually.[43] Expansion of this category of records by adopting the unfocused test proferred by petitioners would blur the line beyond all utility and generate inevitable litigation over the disclosure of countless numbers of documents in the private sector.[44]

Petitioners' sole answer to this argument is that a "restrictive definition" of "agency records" would subvert the "spirit" (Br. 53) and "essence of the Act —freedom of information to the public" (*id.* at 56). But as the court of appeals pointed out, "[i]t is tautology to say that requiring disclosure of grantee records will promote the disclosure policies of FOIA. * * * [D]isclosure is not required by the statute unless those records are agency records. Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all contervailing con-

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[43] For example, we are informed that the FDA processes over 32,000 FOIA requests annually.

[44] Congress has frequently drawn a bright line, even at the cost of some theoretical compromise of policy, when it has been thought important to provide clear and definitive boundaries in order to avoid, among other things, needless litigation. See *FPC* v. *Southern California Edison Co.*, 376 U.S. 205, 215-216 (1964); *Ford Motor Co.* v. *NLRB*, No. 77-1806 (May 14, 1979) (Powell, J., concurring); *cf. NLRB* v. *Robbins Tire & Rubber Co.*, *supra*, 437 U.S. at 224 (sustaining a categorical refusal by the NLRB to produce under the FOIA witness statements in pending NLRB proceedings on the ground that in general such disclosure would interfere with Board proceedings even though in individual cases it might not).

siderations" (App. 233). There is no warrant in the language or background of the FOIA to extend its disclosure obligations to documents, such as the UGDP raw data, that are owned by a private organization and are not in the possession, custody or control of a federal agency. The Court should not take such a drastic step, with its wide-ranging implications, without the clearest indication of congressional intent. See *NLRB* v. *Robbins Tire & Rubber Co.*, 437 U.S. 214, 238 (1978).[45]

[45] In fact, evidence of congressional intent at the time the FOIA was enacted points the other way (see pages 24 to 35, *supra*). In addition, bills that would have extended the FOIA to federal grantees have been introduced in each Congress since the 92d Congress but have never been reported out of committee. See H.R. 11013, 92d Cong., 1st Sess. (1969); H.R. 1291, 93d Cong., 1st Sess. (1973); H.R. 1205, 94th Cong., 1st Sess. (1975); H.R. 3207, 95th Cong., 1st Sess. (1977); H.R. 1465, 96th Cong., 1st Sess. (1979). See also 119 Cong. Rec. 1099 (1973) (remarks of Congressman Young concerning one such bill).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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